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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,178	09/03/2003	Eiji Kanehira	00034CIPC/LH	4334

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT PAPER NUMBER

3739

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/654,178

Applicant(s)

KANEHIRA ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) 2-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 49-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/793,431.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____
- Paper No(s)/Mail Date 9/3/03
- 8/12/05
- 8/23/05
- 1/23/06
- 12/5/05

Information Disclosure Statement

It is noted that the IDS filed December 5, 2005 included a PTO-1449 that was only partially scanned. The foreign references cited on this submission were provided, although they do not appear in the Foreign Patent Documents or Other Documents section of the form. These sections have not been properly scanned. The examiner is citing the three references that were not properly scanned on the attached PTO-892.

Election/Restrictions

Claims 2-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 24, 2006.

Specification

The disclosure is objected to because of the following informalities: the first sentence of the specification should be updated to provide the most current status (i.e. US Patent Number or "abandoned") of the related applications.

Appropriate correction is required.

Claim Objections

Claim 1 is objected to because of the following informalities: the claim is unclear with the phrase "the treatment portion being supported capable of being opened and closed" at lines 5-6. The language is unclear and awkward. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 61-69 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 61 positively recites the human body, which is non-statutory subject matter. Lines 4-5 recites a contact surface "that is brought into contact with said living tissue". The language should be amended to recite the contact surface is "adapted to be brought into contact" to avoid this positive recitation of tissue. Similarly, the language in lines 9-10 of claim 61 appear to recite a similar positive contact between the device and living tissue and should be amended accordingly.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope of claim 61 is unclear in that it positively recites non-statutory subject matter. Correcting the language as suggested above would correct this issue as well. Also, the language describing the contact surface with the living tissue (i.e. the last four

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lines) is very unclear and awkward making it difficult to understand what is being set forth.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 52, 53 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Parins et al (5,908,420).

Parins et al disclose a medical treatment instrument comprising a treatment portion (58) including a pair of grasp portions (60,62) capable of being opened and closed. A frontal operating portion (10) is arranged at the proximal end of the device to actuate the grasp portions. A heat generating portion (122,123) is provided on each grasp portion, and a cutting portion (91,92) is disposed at the grasp portions to cut tissue.

With regard to claim 61, the last four lines of the claim are very unclear. As best understood by the examiner, the Parins et al device may be interpreted to have one contact portion that includes surface (60) and tip (122), and a second contact portion that is just the tip (123). This would yield one contact portion that is smaller than the

other, which appears to be the general idea of the limitation recited at the end of claim 61.

Claims 1 and 49-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Kamiyama et al (5,151,102).

Kamiyama et al disclose a device that includes a pair of grasping jaws (10) and a frontal operation portions (S). A heat generating portion (10a) is provided on each jaw, including a cutting electrode (10f) provided on one of the jaws. A heating unit (2) includes a control to provide power of a first level to coagulate tissue, and at a second level to cut tissue (col. 4, lines 4-22). A set changing element (3) changes the set states, and there are inherently switches within the controller that provides the appropriate current level upon activation of the footswitch. The Kamiyama et al surface is elongate and flat (Figure 4) and has a curved surface in the shape of an arc (when looking from above). Each engaging portion includes a receiving member formed of a resin material. With regard to claim 52, the first engaging portion (Figure 3) includes a protrusion (i.e. the electrode assembly).

Claims 1 and 49-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Kornerup (6,679,882).

Kornerup provides a forceps device with a cutting member (22). Electrical energy is provided at different energy levels to the jaw area to coagulate or cut tissue using various switching means. Again, the grasp members may be considered elongate

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and flat (i.e. along the grasping edge) or curved in the shape of an arc (when looking from above).

Claims 1, 49-56 and 61-69 are rejected under 35 U.S.C. 102(e) as being anticipated by Yamauchi et al (6,273,887).

The Yamauchi et al patent has a common inventor with the instant application and discloses substantially the same device. It includes a forceps device with means to provide either a cutting or a coagulating energy level to the jaws (Figure 27). The jaws may take various configurations and includes a resin material located within the jaw members. Yamauchi et al disclose various different embodiments for the shapes of the grasping members similar to those disclosed in the instant application.

Claims 1, 49-54 and 61-68 are rejected under 35 U.S.C. 102(e) as being anticipated by Wrublewski et al (6,174,309).

Wrublewski et al disclose yet another tissue grasping and cutting device that includes a pair of grasping elements with electrical connections to provide either a coagulating or a cutting current to tissue. A plurality of switches are inherently included to provide the different energy levels (col. 2, lines 55-59). A cutting member is also provided for cutting tissue. The grasping surfaces may be elongated and flat (Figure 6C) or may have a rounded shape (Figure 6A, when looking from above) or may be curved along the length (Figure 6B). Each jaw has a differently shaped contact surface yielding different contact areas and Wrublewski et al disclose slip prevention portions

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(i.e. notches as seen in the cross-section views of Figures 5A and 5B) as well as non-stick coatings on the electrode (col. 2, lines 20-25). The cross sections of the Figure 5 embodiments show various contact surfaces, including rectangular, notched and chamfered surfaces.

Claims 61-65 and 67-69 are rejected under 35 U.S.C. 102(e) as being anticipated by Baker (6,113,598).

Baker et al discloses a surgical instrument comprising a distal end portion including a pair of holding portions (30A, 30B). An operation portion (i.e. handle) is provided at the proximal end for opening and closing the holding portions, and each holding portion includes a heat generating portion (i.e. electrode) formed in a contact portion. The heat generating portions may take various shapes and have different contact areas (see Figures), and may be arcuate in cross-section (Figures 3A,3B). The body of the holding portions may be made of a flexible, heat resistant material such as rubber (col. 13, lines 5-10). The heat generating portion may also be made of a flexible material. Figures 12A-12C show the heat generating portion (132) deforming.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 55-60 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wrublewski et al ('309) in view of the teaching of Baker ('598).

The Wrublewski et al reference has been addressed previously. The Wrublewski et al jaws including a receiving member (i.e. portion of jaw that holds the electrode), but fails to disclose the particular materials used to make the receiving members (i.e. jaws).

As asserted previously, Baker discloses the use of various materials for making the jaw members to support the heating electrodes. In particular, Baker teaches the use of flexible materials such as rubber (col. 13, lines 5-10). The examiner maintains that the use of any other well known material, including a resin or a fluoroplastic, would be deemed obvious design considerations as these materials are generally well-known and often used as support materials in RF heating devices.

To have formed the Wrublewski et al jaws from any well-known material, such as rubber, to provide a heat resistant support for the electrodes would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Baker.

Claims 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamauchi et al ('887) in view of the teaching of Baker ('598).

The Yamauchi et al device has been addressed previously. While Yamauchi et al disclose various embodiments for the jaws, there is no disclosure that the jaw members include a receiving member made from rubber, gel or fluoroplastic as set forth in claims 57-59.

As asserted previously, Baker discloses the use of various materials for making the jaw members to support the heating electrodes. In particular, Baker teaches the use of flexible materials such as rubber (col. 13, lines 5-10). The examiner maintains that the use of any other well known material, including a resin, gel or a fluoroplastic, would be deemed obvious design considerations as these materials are generally well-known and often used as support materials in RF heating devices.

To have formed the Yamauchi et al jaws from any well-known material, such as rubber, to provide a heat resistant support for the electrodes would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Baker.

Claims 49-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker ('598) in view of the teaching of Kamiyama et al ('102).

Baker provides a device having first and second tissue engaging members and a heating unit (i.e. electrodes) for heating tissue as set forth in the claims. However, Baker fails to disclose the specific current supply and control element that provides two different current levels for cutting and coagulation of tissue. It is noted that Baker does provide a mechanical cutter (Figures 13-14) for cutting tissue after coagulation.

Kamiyama et al, as discussed earlier, disclose an analogous forceps device for clamping and coagulating tissue. In particular, Kamiyama et al specifically disclose a control means to provide two separate current levels to the electrode. One level is effective to coagulate tissue, and another is used to cut tissue.

To have provided the Baker device with two separate current levels to allow for cutting of tissue after tissue coagulation is deemed to be an obvious consideration for

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one of ordinary skill in the art, particularly since Baker teach that it is advantageous to cut tissue after coagulation and further in view of Kamiyama et al who teach that it is known to do so electrosurgically with a separate cutting signal.

Conclusion

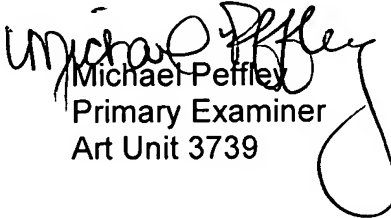
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hooven (6,086,586), Mulier et al (6,096,037), Feinberg et al (5,458,598) and Austin et al (5,702,390) disclose various other bipolar forceps devices for cutting and/or coagulating tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

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March 27, 2006